UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

MARY JACKSON, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 2:12-CV-196
	§	
WYETH LLC; fka WYETH; dba WYETH INC., *et al*,	§	
	§	
	§	
Defendants.	§	

ORDER

Mary Jackson, along with her husband (together Jackson), sued Wyeth Pharmaceuticals Inc., Wyeth LLC, and Pfizer Inc. (jointly Wyeth) and Schwarz Pharma, Inc. n/k/a UCB, Inc. (Schwarz), alleging that Mary Jackson suffers from tardive dyskinesia as a result of ingesting the pharmaceutical drug Reglan and/or its generic equivalent metoclopramide over an extended period of time. She alleges that Wyeth and Schwarz, both of which manufactured and sold Reglan, knew of the dangers of long-term exposure to the drug and failed to provide appropriate warnings with the packaging.

Before the Court are summary judgment motions filed by Wyeth (D.E. 104) and Schwarz (D.E. 106). Schwarz seeks summary judgment based on Texas products liability law, which provides a manufacturer and seller with a presumption that there is no liability for a product when it and its packaging were approved by the Federal Food and Drug Administration (FDA). Wyeth has filed its own summary judgment motion on the same non-liability presumption, joining Schwarz's briefing on the issue. Likewise, Jackson incorporated by reference her briefing on that issue in response to the Schwarz motion. Wyeth also seeks summary judgment on the basis that Jackson did not ingest its product.

For the reasons set out below, the Court GRANTS Schwarz's motion (D.E. 106) and GRANTS IN PART and DENIES IN PART Wyeth's motion (D.E. 104).

A. Jackson's Exposure to Reglan

In its motion, Wyeth contends that it manufactured only the name-brand form of the drug—as Reglan—and that it had ceased production and sales over a year prior to the time that Jackson began using the drug. Wyeth claimed that, in discovery, Jackson had produced all of her pharmacy records and that it was undisputed that she had never received Reglan. Arguing that it cannot be held liable for injuries caused by a product it did not design, manufacture, or sell, specifically in the context of "copy-cat" drugs that Jackson did ingest, Wyeth seeks summary judgment.

In response, Jackson produced summary judgment evidence demonstrating that, on one occasion, the pharmacy had dispensed to her a prescription of Reglan, accompanied by Wyeth's National Drug Code number. Wyeth filed its reply in support of its motion arguing that Jackson would still have to prove her case that she ingested Wyeth's Reglan and that it (as opposed to another manufacturer's metoclopramide) caused her injury. But Wyeth offered no reason that Jackson's evidence that she had received Reglan was insufficient to raise a disputed issue of material fact regarding its liability. Because Wyeth has not demonstrated that Jackson failed to use its product, its request for summary judgment on that basis is DENIED.

B. The Non-Liability Presumption

Both Wyeth and Schwarz invoke the Texas products liability statute, Tex. Civ. Prac. & Rem. Code 82.007(a), which imposes a presumption against liability for pharmaceutical products when the products and their warnings have been approved by the FDA for the purpose to which they were put. This applies, regardless of the theory of liability that Plaintiff pleads. *Id.* §

82.001(2) (defining a "products liability action" to include a number of identified theories involving injuries and damages caused by a product—such as negligence and breach of warranty—and "any other theory or combination of theories."); *Lashley v. Pfizer, Inc*., 750 F.3d 470, 477 (5th Cir. 2014) (per curiam) (noting the broad definition of "products liability action" in Texas law). There is no question that Reglan and metoclopramide, along with their packaging, were approved by the FDA and that Jackson's use was consistent with that approval.

Thus the question is whether Jackson can rebut the presumption against liability. One method for rebutting the presumption under the statute is to show that the defendant perpetrated a fraud on the FDA in connection with the warnings accompanying the product. Tex. Civ. Prac. & Rem. Code § 82.007(b)(1). Jackson's argument is that Defendants defrauded the FDA by withholding from, or misrepresenting to, the FDA information about the drug, including failure to disclose that extended use can cause tardive dyskinesia.

However, this rebuttal method is not a wide open forum for evidence of a defendant's malfeasance or nonfeasance. Rather, it is now well-established that, to prove such fraud-on-the-FDA, the Plaintiff must show that the FDA, itself, has pursued Defendants and prevailed on such claims of violations of the federal law governing disclosures and reports on regulated pharmaceuticals. *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 379-80 (5th Cir. 2012). That is because FDA regulatory statutes preempt state law claims in order to maintain the necessary balance of interests weighed by the legislature. *Id*. (applying *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) ("[T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.")). Because the FDA has all the necessary tools, but has not found Wyeth or Schwarz to have defrauded the agency,

the desired rebuttal must fail and § 82.007(a) provides Wyeth and Schwarz with a complete defense.

To avoid this result, Jackson asserts five arguments. First, she contends that Defendants should not be permitted to evade liability where they have purposefully and knowingly made misrepresentations to Jackson and to the FDA. In other words, Jackson asks this Court to reject controlling case law or hold that allegations of "knowing" or "purposeful" conduct provides an exception to the FDA preemption.

This Court is bound to follow Fifth Circuit decisions and has no reason to distinguish this case from *Lofton*. Furthermore, this Court finds no appreciable difference between the elements of "fraud" and Jackson's allegations of knowing or purposeful conduct. In fact, such conduct is subsumed within many, if not all, definitions of "fraud." *E.g.*, *Spring St. Partners-IV, L.P. v. Lam*, 730 F.3d 427, 442 (5th Cir. 2013) (applying Texas law); *DeSantis v. Wackenhut Corp*., 793 S.W.2d 670, 688 (Tex. 1990). With respect to the application of § 82.007(b)(1), this Court follows *Lofton* and rejects the argument that this case involves allegations that necessarily fall outside of the fraud-on-the-FDA rebuttal provision, which requires evidence that the FDA found Defendants to be in violation of federal regulations.

Second, Jackson suggests that there is a disputed issue of material fact whether Defendants' promotion of the drug was for an unapproved indication. Yet Jackson's own complaint admits that her ingestion of Reglan/metoclopramide was for an approved indication, gastroexophageal reflux disease. D.E. 79, p. 6, 8. Whether it is true, then, as Jackson alleges, that Defendants promoted the use of Reglan/metoclopramide for an unapproved indication does not matter. Such conduct would have no causal relationship with her claim. It is not probative of any issue in this case. The Court rejects Jackson's second argument.

Third, she argues that the motions are premature because discovery has not been completed. Yet Jackson has not articulated how discovery will provide evidence of an FDA finding of fraud, which is the only relevant basis upon which she may rebut the non-liability presumption to which Defendants are entitled. Indeed, courts have established that the non-liability presumption in Texas law cannot be rebutted under § 82.007(b)(1) because there is no FDA finding of fraud—a matter that would not vary from case to case or require discovery. Again, because promotion for an unapproved indication would be irrelevant, discovery on that issue is not warranted either. The Court rejects Jackson's argument that the motions are premature and that additional discovery is necessary.

Fourth, Jackson argues that § 82.007(b)(1) violates the open courts provision of the Texas Constitution, which states, "All courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law." Tex. Const. art. 1, § 13. According to Jackson, if a person is unable to rebut the non-liability presumption of § 82.007(a) in the manner intended by § 82.007(b)(1) because the FDA has failed to issue a finding of fraud to trigger that provision, then that person has been deprived of a meaningful remedy. Under that syllogism, the obstacle—§ 82.007(b)(1)—must be held unconstitutional and severed. *See generally, Villas at Parkside Partners v. City of Farmers Branch*, 496 F. Supp. 2d 757, 773-74 (N.D. Tex. 2007).

This argument was considered and rejected in *Murthy v. Abbott Labs*., 847 F. Supp. 2d 958, 976 n.8 (S.D. Tex. 2012). Finding § 82.007(b)(1) unconstitutional does not help Jackson because § 82.007(a)'s presumption would still bar her claim. And as the *Murthy* court held, the law does not require finding that the rest of § 82.007 is invalid even if the court were to consider § 82.007(b)(1) invalid. Moreover, Jackson's § 82.007(b)(1) rebuttal is not completely eliminated

by the requirement that the FDA act. If her claims of fraud are valid, she can petition the FDA to take the necessary steps to issue a finding that triggers her § 82.007(b)(1) rights. 21 C.F.R. § 10.30. This is the regulatory framework that the legislatures have devised in an effort to balance the competing interests of drug manufacturers, patients, and the public. The Court declines to invalidate any part of § 82.007 on Jackson's arguments brought pursuant to the Texas Constitution.

Fifth, Jackson asserts that her claims for design defect and deceptive trade practices survive § 82.007. This argument fails to acknowledge the factual basis of the claims and is inconsistent with the statute. Under Texas law, a plaintiff may not, by simply using different language, cast a claim in a manner that is inconsistent with its substance in order to evade a statutory limitation. It is the underlying nature of the claim that governs the theory under which it must be brought. *MacGregor Med. Ass'n v. Campbell*, 985 S.W.2d 38, 40 (Tex. 1998). Section 82.001(2) defines a product liability action as one addressing injury caused by a product, regardless of the legal theory under which it is couched. And § 82.007(a) applies to "a failure to provide adequate warnings or information with regard to a pharmaceutical product." *See generally*, *Eckhardt v. Qualitest Pharmaceuticals, Inc*., 751 F.3d 674, 678 (5th Cir. 2014); *Phares v. Actavis-Elizabeth*, 892 F. Supp. 2d 835, 839, 844 (S.D. Tex. 2012). Jackson's complaints, however labeled in her pleading, trigger § 82.007(a)'s non-liability presumption and entitle Wyeth and Schwarz to their defense.

To the extent that Wyeth and Schwarz seek summary judgment on the basis of the non-liability presumption, their motions are GRANTED.

CONCLUSION

For the reasons set out above, the Court GRANTS Schwarz's motion for summary judgment (D.E. 106), GRANTS IN PART Wyeth's motion for summary judgment (D.E. 104) with respect to its defense under § 82.007(a) and DENIES IN PART Wyeth's motion with respect to its claim that Jackson did not ingest its product.

ORDERED this 27th day of January, 2015.

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE